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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,755	11/28/2000	Hans-Michael Wenz	7414.0020-03	8421

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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,755	WENZ, HANS-MICHAEL	
	Examiner	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *131-133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *131-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 11, 2003 has been entered.

Claim Interpretation

2. In claims 131-133, the term "amplification product" is read as a nucleic acid that is not chemically synthesized. Since DNA or RNA can be amplified, in either single stranded (as in asymmetric PCR) or double stranded form (as in regular PCR or in mini or maxi preps from E. coli, for example), any non chemically synthesize DNA will meet the requirement of being an "amplification product."

3. In claims 131-133, the term "primer specific portion", whether as first or second portion is read as any sequence of nucleic acid whatsoever that is more than 3 nucleotides in length. As Sommers et al (Nucleic Acids Research (1989) 17(16)6749) notes regarding the minimal homology requirements for PCR primers "Primers with a length between 17-20nt need at least three homologous nucleotides at their 3' end for successful priming." So the minimal requirement for a primer specific portion of an amplification product is three homologous nucleotides.

4. In claims 131-133, the term "addressable support specific portion" is interpreted as a nucleic acid that can bind a complementary nucleic acid probe. Any nucleic acid sequence whatsoever can meet this limitation since any nucleic acid sequence can hybridize to the complementary sequence by Watson-Crick base pairing.

5. In claims 131-133, the term "mobility modifier" is read (in context of the claim that requires at least two such modifiers) as requiring two nucleic acids that can bind to two different "amplification products" (as broadly defined above) which differ either in their length, or in the label that is attached to them.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 131-133 are rejected under 35 U.S.C. 102(b) as being anticipated by Halminen et al (Cytokine (January 1999) 11(1):87-93).

Halminen teaches a composition comprising

(i) a plurality of different amplification products (see page 87, subheading "General outline of the assay" and page 88, column 1) which comprise;

(a) a first primer specific portion (see page 88, column 1 and table 1, where every amplification product is amplified using two different primers and consequently has two primer specific portions relating to each of the two separate primers),

(b) a second primer specific portion (see page 88, column 1 and table 1, where every amplification product is amplified using two different primers and consequently has two primer specific portions relating to each of the two separate primers)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see page 88, figure 1, column 1 and table 1, where the probes hybridize to the amplification product between the primers and where each probe is different)

and

(ii) at least two different mobility modifiers, (see table 1 and page 89, where the three probes, IFN-g, IL-4 and b-ACT represent three different mobility modifiers that bind to the addressable support specific portion) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See table 1 and page 89, where the three probes bind to the amplified PCR products),

(b) a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers (see page 88, table 1 and page 89, where each of the probes has a different chemical label with a different molecular mass that would result in a different mobility)

With regard to claim 132, all of the addressable support specific portions are substantially the same length (see table 1, where each probe is 20 nucleotides in length),

With regard to claim 133, each of the mobility modifiers has a lanthanide label (see page 88, table 1).

8. Claims 131-133 are rejected under 35 U.S.C. 102 (e) as being anticipated by Wittwer et al (U.S. Patent 6,140,054).

Wittwer teaches a composition comprising

(i) a plurality of different amplification products (see column 24, lines 35-50, where Wittwer indicates that two primer sets and two probes were used (see column 24, line 40) which comprise;

(a) a first primer specific portion (see column 24, lines 35-50, where every amplification product is amplified using two different primers and

consequently has two primer specific portions relating to each of the two separate primers),

(b) a second primer specific portion (see column 24, lines 35-50, where every amplification product is amplified using two different primers and consequently has two primer specific portions relating to each of the two separate primers)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see column 24, lines 35-50 , and column 26, table 1, where the probes hybridize to the amplification product between the primers and where each probe is different)

and

(ii) at least two different mobility modifiers, (see column 26, table 1, where the two fluorescent probes represent two different mobility modifiers that bind to the addressable support specific portion) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See, column 26, table 1 and column 24, lines 35-67, where the probes bind to the amplified PCR products),

(b) a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers (see column 26, table 1, where each of the probe sets has a different fluorescent label, each having both a fluorescein

and a Cy-5 label so that the composition comprises mobility modifiers with a different molecular mass that would result in a different mobility).

With regard to claim 132, all of the addressable support specific portions are substantially the same length (see column 26, table 1, where the term "substantially" is not defined and therefore the probes meet this requirement)

With regard to claim 133, each of the mobility modifiers has a fluorescent label (see page 88, table 1).

9. Claims 131-133 are rejected under 35 U.S.C. 102 (b) as being anticipated by Grossman et al (Nucleic Acids Research (1994) 22(21):4527-4534).

Grossman teaches a composition comprising

(i) a plurality of different amplification products (see page 4529, column 2, subheading "Multiplex PCR amplification of CFTR exons", where Grossman indicates that two primer sets and many probes were used (see page 4529, column 2 and Tables II and III) which comprise;

(a) a first primer specific portion (see page 4529, column 2, where every amplification product is amplified using two different primers and consequently has two primer specific portions relating to each of the two separate primers),

(b) a second primer specific portion (see page 4529, column 2, where every amplification product is amplified using two different primers and consequently has two primer specific portions relating to each of the two separate primers)

(c) and an addressable support specific portion, between the primer specific portions that is different for each of the amplification products (see page 4529, column 2, and Tables II and III, where the probes hybridize to the amplification product between the primers and where each probe is different)

and

(ii) at least two different mobility modifiers, (see page 4529, table III), where each of the different represent a different mobility modifier that bind to the addressable support specific portion) which further comprises:

(a) a tag complement for specifically binding the addressable support specific portion of one of the plurality of different amplification products (See page 4529, table III and column 2, where the probes hybridize to the amplified PCR products),

(b) a tail which imparts to each mobility modifier a distinct mobility relative to the other mobility modifiers (see page 4529, table III and page 4531, figure 3(a) and column 2), where each of the probes has a different tail that is shown to result in a different mobility).

With regard to claim 132, all of the addressable support specific portions are substantially the same length (see page 4529, table III, where the term "substantially" is not defined and therefore the probes inherently meet this requirement).

With regard to claim 133, each of the mobility modifiers comprises an HEO unit as well as a fluorescein (see page 4531, column 1).

Response to Arguments

10. Applicant's arguments filed September 11, 2003 are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1634